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BlueShield**

Federal Employee Program.

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5.75.028

Section:	Prescription Drugs	Effective Date:	January 1, 2024
Subsection:	Neuromuscular Drugs	Original Policy Date:	May 24, 2019
Subject:	Vyndaqel Vyndamax	Page:	1 of 5

Last Review Date: December 8, 2023

Vyndaqel Vyndamax

Description

Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)

Background

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) are selective stabilizers of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, which is the rate-limiting step in the amyloidogenic process (1).

Regulatory Status

FDA-approved indication: Vyndaqel and Vyndamax are indicated for the treatment of the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization (1).

Vyndaqel and Vyndamax are not substitutable on a per mg basis (1).

Vyndaqel and Vyndamax have not been studied in: New York Heart Association (NYHA) class IV, primary light chain amyloidosis, prior liver or heart transplantation, or implanted cardiac mechanical assist device (1).

The safety and effectiveness of Vyndaqel and Vyndamax in pediatric patients less than 18 years old have not been established (1).

Related policies

Onpattro, Tegsedi

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Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vyndaqel and Vyndamax may be considered **medically necessary** if the conditions indicated below are met.

Vyndaqel and Vyndamax may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Cardiomyopathy

AND ALL of the following:

1. Patient has **ONE** of the following:
 - a. Genetic confirmation of hereditary transthyretin-mediated amyloidosis (ATTR)
 - b. Wild type transthyretin-mediated amyloidosis (ATTR)
2. Confirmation of amyloid deposits showing cardiac involvement by **ONE** of the following:
 - a. Biopsy
 - b. Nuclear imaging
 - c. Diagnostic cardiac imaging
3. Prescribed by a cardiologist or the prescriber has consulted with a cardiologist
4. Prescriber will monitor patients taking NSAIDs, calcium channel blockers (CCBs), or digoxin for toxicity

AND NONE of the following:

1. Heart failure due to causes other than ATTR
2. Light-chain amyloidosis
3. History of heart or liver transplantation
4. Implanted cardiac mechanical assist device, such as left ventricular assist device (LVAD)

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- a. Implanted devices for heart rhythm such as a pacemaker or cardiac defibrillator are allowed
- 5. Severe malnutrition

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Cardiomyopathy

AND ALL of the following:

1. Patient has **ONE** of the following:
 - a. Genetic confirmation of hereditary transthyretin-mediated amyloidosis (ATTR)
 - b. Wild type transthyretin-mediated amyloidosis (ATTR)
2. Patient has been assessed for improvement and has experienced a clinical benefit from therapy
3. Prescribed by a cardiologist or the prescriber has consulted with a cardiologist
4. Prescriber will monitor patients taking NSAIDs, calcium channel blockers (CCBs), or digoxin for toxicity

AND NONE of the following:

1. Heart failure due to causes other than ATTR
2. Light-chain amyloidosis
3. History of heart or liver transplantation
4. Implanted cardiac mechanical assist device, such as left ventricular assist device (LVAD)
 - a. Implanted devices for heart rhythm such as a pacemaker or cardiac defibrillator are allowed
5. Severe malnutrition

Policy Guidelines

Pre - PA Allowance

None

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Prior - Approval Limits

Quantity

Strength	Quantity
Vyndaqel 20 mg capsules	360 capsules per 90 days
Vyndamax 61 mg capsules	90 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Vyndaqel (tafamidis meglumine) and Vyndamax (tafamidis) are selective stabilizers of transthyretin (TTR). Tafamidis binds to TTR at the thyroxine binding sites, stabilizing the tetramer and slowing dissociation into monomers, which is the rate-limiting step in the amyloidogenic process. The safety and effectiveness of Vyndaqel and Vyndamax in pediatric patients less than 18 years old have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Vyndaqel and Vyndamax while maintaining optimal therapeutic outcomes.

References

1. Vyndaqel and Vyndamax [package insert]. New York, NY: Pfizer Inc.; April 2023.

Policy History

Date	Action
May 2019	Addition to PA
June 2019	Annual review
September 2019	Annual review. Addition of requirement for prescriber to monitor for NSAID, CCB, or digoxin toxicity and no heart failure not due to ATTR, light-chain amyloidosis, transplant, severe malnutrition per SME
December 2019	Revised requirement to patient must have wild type ATTR or genetic confirmation of hereditary ATTR
March 2020	Annual review and reference update

5.75.028

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August 2020	Revised requirement that patients cannot have an implanted cardiac mechanical assist device, such as left ventricular assist device (LVAD) but implanted devices for heart rhythm are allowed
September 2020	Annual review
December 2021	Annual review and reference update
December 2022	Annual review. Changed policy number to 5.75.028
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.